**July 8, 2002** 

## **MERIT REVIEW PROGRAM**

- **1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook announces programmatic changes to the Merit Review Program in the Rehabilitation Research and Development (RR&D) Service.
- **2. SUMMARY OF MAJOR CHANGES:** This VHA Handbook establishes new policy and procedures for the VHA Rehabilitation Research and Development's Merit Review Program.
- **3. RELATED DOCUMENTS:** VHA Directive 1203.
- **4. RESPONSIBLE OFFICE:** The Office of Rehabilitation Research and Development (124) is responsible for the contents of this Handbook.
- **5. RESCISSION:** VHA Manual M-3, Part IV, and VHA Directive 10-87-32 dated April 13, 1987, is rescinded.
- **6. RECERTIFICATION**: This document is scheduled for re-certification on or before the last working date of July 2007.

S/ Jonathan B. Perlin, M.D. for Robert H. Roswell, M.D. Under Secretary for Health

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#### MERIT REVIEW PROGRAM

#### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides policy and guidance related to the Rehabilitation Research and Development (RR&D) Merit Review program, and submission of Investigator Initiated Research (IIR) Merit Review proposals.

#### 2. BACKGROUND

- a. The Department of Veterans Affairs' (VA) RR&D program supports research relevant to the rehabilitative needs of veterans, including emphasis in the areas of:
  - (1) Prosthetics,
  - (2) Orthotics,
  - (3) Mobility,
  - (4) Orthopedics,
  - (5) Disabilities as a consequence of aging,
  - (6) Neurological dysfunction,
  - (7) Spinal cord injury restoration and/or rehabilitation,
  - (8) Communication disorders,
  - (9) Sensory and cognitive aids,
  - (10) Dementia,
  - (11) Chronic psychiatric disorders,
  - (12) Rehabilitation outcomes, and
  - (13) Engineering applications to rehabilitation.
- b. Rehabilitation is assuming a role of importance as a scientific discipline. As the population of veterans with chronic disease expands, due in part to improved survival following catastrophic events, the need for research increases. Rehabilitation's fundamental clinical goal is to maximize functional recovery. This often means teaching compensatory techniques and providing adaptive equipment. The long-term effects on outcomes of many traditional approaches remain unproven, and as rehabilitation moves forward, researchers must examine efficacy to allow its medical practice to be truly evidence based.

c. Optimal care also requires that VHA seize the opportunity to devise therapies that will lead to restoration of function. It is necessary to reexamine conventional rehabilitation methods in order to promote better rehabilitation. Research needs to translate bench findings to the clinical arena. Rehabilitation techniques based on findings in animal models, and intended to enhance neural activity in fully or partially impaired pathways, have unique promise, especially in stroke and spinal cord injury patients. A crucial issue is the extent to which external experience influences general health, quality of life and genuine recovery. VA RR&D is committed to advancing and expanding the field of rehabilitation and to creating increased research capacity within VA.

#### 3. MERIT REVIEW

The RR&D Service Investigator Initiated Research (IIR) Merit Review process is the principal mechanism for competitive funding of VA rehabilitation research. It provides RR&D Service with a critique of the scientific quality and clinical relevance of the entire research, development and evaluation effort, and indicates a recommended level of budgetary support.

#### 4. SCOPE

- a. A Scientific Review and Evaluation Board reviews all proposal applications for merit. Upon completion of this process, the Director of RR&D recommends to the Chief Research and Development Officer (CRADO) funding of projects on the basis of the:
  - (1) Scientific merit and feasibility of the proposed research; and
- (2) Significance and importance of the proposed research to the mission of RR&D, and whether it significantly adds to the state-of-the-art in the field of rehabilitation.
- b. Acknowledgement of VA Support. Publication or commercialization of a product that is based on research supported by VA must cite an acknowledgement of VA, and the VA health care facility must be identified. When VA provides half or more of the salary support for the Principal Investigator (PI), it shall be named first, regardless of whether VA is the primary source of funding, or where the funds are administered. Acknowledgement must reference support provided by RR&D Service and identify the investigator's VA employment title. Commercial literature must reference the Department of Veterans Affairs, RR&D Service (see VHA Handbook 1200.19)

#### 5. **DEFINITIONS**

- a. <u>Letter of Intent (LOI).</u> An approved LOI is required before submitting a proposal for a full research project or a pilot study proposal. Investigators will be advised as to the appropriateness of the planned project for RR&D Merit Review. Please go to http://www1.va.gov/resdev/funding/unified-cal04.cfm for dates.
- b. **Proposal Deadlines.** RR&D deadlines for Merit Review can be found at http://www1.va.gov/resdev/funding/unified-cal04.cfm. The RR&D Scientific Review and Evaluation Board meets to review proposals in Summer and Winter.

- c. <u>IIR Program.</u> The RR&D IIR Merit Review process includes <u>two types of proposals</u> for submission to RR&D Service.
- (1) <u>Full Research Proposals</u> are funded for up to \$250,000 per year for up to 3 years (see App. B).
- (2) <u>Pilot Study Proposals</u> are funded up to \$50,000 and are limited to 1 year. A pilot proposal is a new study to establish feasibility or to develop data, a technique, concept or procedure, which is preliminary to undertaking a full Merit Review project. Complete but brief information is needed. An explanation needs to be given as to why this type of study is needed in lieu of a full-scale project. Pilot proposals are prepared using the same format for submitting a Merit Review proposal (see App. B).
- d. <u>Merit Review Appeal Procedures.</u> Information regarding the Merit Review Appeal process is found in Appendix C.
- e. <u>Investigator Eligibility.</u> RR&D Service is an intramural research program. All applicants (i.e., the PI and any Co-PI(s)) for VA research funds must hold a minimum 5/8 VA salaried position before a research project can be funded. Individuals with less than a 5/8 VA appointment are encouraged to seek at least a 5/8 VA appointment (see VHA Handbook 1200.15).
- f. <u>Consultants.</u> Applicants need to be aware that numerous restrictions apply to payment of consultants (non-VA employees). Should the services of a consultant be required to conduct a research project, the PI is advised to explore current applicable VA rules and regulations before developing the proposal budget. Consultants (individuals or firms) who are paid for advisory and assistance services under a letter of agreement (Title 48 Code of Federal Regulations (CFR) § 837.270) cannot receive more than \$500 per procurement action, or more than \$2,500 per year in consulting fees.
- g. <u>Human Subjects</u>. Investigations involving human subjects will not be reviewed until the VA medical facility, or affiliated university Institutional Review Board (IRB), has approved them for Human Studies. A completed and current (dated no earlier than 1 year before the receipt date for which the application is submitted) VA Form 10-1223, Report on Subcommittee on Human Studies, must be submitted with the proposal. It must be accompanied with VA Form 10-1086, VA Research Consent Form, that will be presented to each subject or legally responsible guardian prior to the subject's participation in the study. *NOTE:* Prior to Merit Review, all PI's and other investigators on a research proposal involving human subjects, including biological specimens, must be certified as having met all current educational requirements for the protection of human subjects as mandated by the Office of Research and Development (ORD) (see VHA Handbook 1200.5).
- h. <u>Animal Studies and Veterinary Medical Review.</u> Applications involving the use of animals must contain a completed Animal Component of Research Protocol (ACORP) that is dated no earlier than 1 year before the receipt date for which the application is submitted. Prior to Merit Review, the Chief Veterinary Officer reviews research proposals utilizing animals (see VHA Handbook 1200.7).

- i. <u>Biohazards and Radioisotopes Impact.</u> Proposals containing procedures that constitute a potential biohazard must be accompanied by a current explanation of safety precautions to be undertaken. A statement from the local VA medical facility or University Biohazard Subcommittee must be submitted with the proposal. VA Form 10-0373, Proposal Safety Information and Certification of Proposal Approval, must be completed and signed by appropriate personnel (see VHA Handbook 1200.8).
- j. <u>Off-Site Research.</u> An investigator who seeks permission to perform research outside of a VA medical center, VA-owned or VA-leased space, must request a waiver to perform the research off-site (see VHA Handbook 1200.16).
- k. <u>Conflict of Interest Survey.</u> A Conflict of Interest survey form for every PI and Co-PI must accompany the proposal submission (see VHA Handbook 1200.7).
- 1. <u>Intellectual Property.</u> Inventions and transfer of new scientific discoveries (see VHA Handbook 1200.18).

### 6. APPLICATION REQUIREMENTS

Specific requirements and guidelines for letters of intent and research proposals, as well as other aspects of the RR&D Merit Review program, are presented in Appendices A through G.

# INSTRUCTIONS FOR SUBMITTING A LETTER OF INTENT TO REHABILITATION RESEARCH AND DEVELOPMENT SERVICE FOR A MERIT REVIEW PROPOSAL

**1. POLICY:** All applicants for research support through Rehabilitation Research and Development (RR&D) Service are required to submit a Letter of Intent (LOI). A description of the proposed project in terms of its objectives, rationale, methods, participants, resource requirements, expected outcomes, technology transfer implications, and the impact on the health care delivery system for veterans should be included. An investigator may submit a proposal only after an LOI has been reviewed and approved by RR&D. Applicants <u>may</u> submit more than one LOI per review cycle.

#### **2. PURPOSE:** The LOI review:

- a. Confirms that each proposal forwarded to RR&D falls within the announced priority research areas or in those areas cited in subsequent special RFP solicitations. *NOTE:* The Associate Chief of Staff (ACOS) for Research should carefully review the mission of each Service within Research and Development (R&D) to ensure that proposals are sent to the most appropriate Service for review.
- b. Confirms that each proposal forwarded to RR&D has the potential to add to and improve the knowledge base in specific research areas and the proposed research has near-term applicability, as opposed to more basic science and long-term research objectives.
- c. Identifies and resolves major problem areas such as Department of Veterans Affairs (VA) investigator eligibility, and VA off-site research issues prior to the submission of a full proposal.
- d. <u>Special solicitations or Request for Proposal (RFP)</u>. An RFP can be announced at any time and have special requirements and due dates that are contained in the specific RFP. *NOTE: Refer to specific solicitation number and instructions for submission information.*
- e. <u>Submission Information.</u> Applicants for research support to RR&D Service <u>may</u> submit more than one LOI per review cycle. Once an LOI is approved, an investigator has up to two Merit Review rounds to submit a proposal for review. Each proposal submission, including pilot study proposals, must be preceded by an approved LOI. An unfunded, revised proposal may be resubmitted directly for the next merit review cycle without first submitting an LOI. However, it is required that a completed LOI Cover Page (VA Form 10-1313-13, VA Research/Development Program) be submitted at least one month prior to the proposal due dates.
- f. <u>Due Date.</u> The LOI process was designed to provide a systematic and defined approach to enhance the development of successful proposals for RR&D funding, to allow investigators as much time as possible to develop and fine tune proposals, and to permit adequate time for required reviews and approvals at the facility level. Please see table at <a href="http://www1.va.gov/resdev/funding/unified-cal04/cfm">http://www1.va.gov/resdev/funding/unified-cal04/cfm</a>.

- g. **Review Process.** An LOI will be reviewed for scientific merit, relevance to veterans' needs, RR&D Service priority areas, and whether the proposed research advances the knowledge base of rehabilitation research. Written notification of approval or disapproval will be issued through the Office of the ACOS for R&D at the Principal Investigator (PI)'s VA facility. An investigator must have an approved LOI prior to submitting a proposal to RR&D for Merit Review.
- h. **Off-Site Research.** VHA policy mandates that VA-funded research be performed within VA medical centers or VA leased space, except when off-site facilities provide unique research opportunities. Off-site waiver requests must be submitted to the Director, RR&D Service at least 60 days prior to the due date for receipt of proposals. Proposals for off-site research submitted without an approved off-site waiver will be returned without review (see VHA Handbook 1200.16).
- i. **Eligibility.** All applicants (i.e., the PI and any Co-PIs) for VA research funds must hold a minimum 5/8 VA salaried position before a research project can be funded (see VHA Handbook 1200.15).

### 3. FORMAT

- a. The LOI Cover Sheet (VA Form 10-1313-13) must be submitted with a LOI. Check applicable categories in each box and type in all requested information. *NOTE:* In Box #3 marked *Program and Level*, state priority area. For *Pilot Projects* check *Other* and type in *Pilot*.
- b. The information contained in the LOI is not to exceed three pages of text, not including one page of cited references. An additional page about the PI's experience in the proposed research area is allowed.
- c. Use at least 1-inch margins on all sides and a font that is easy to read and reproduce. Any LOI using low quality or small print will be returned without review. Use **bold type** for all major section headings, and separate major sections with a double space.
- d. **Text Pages (not exceeding three).** At the top of each page, type PI's name and Project Title and date. In the following order, state:
- (1) **Purpose.** List the goals and specific objectives of the proposed research; clearly state the question to be addressed, hypothesis to be tested, methods, concepts, systems, or devices to be developed or evaluated. (Approximately ½ page)
- (2) **Background.** State the scientific rationale for the proposed research and its relationship to other major research findings. Explain how this research will advance knowledge in

rehabilitation research. Describe the significance of the research and how it relates to RR&D priority areas. Indicate how this research directly benefits veterans and how it contributes to the quality of services provided by VA. (Approximately ½ page)

- (3) **Expected Outcomes or Products.** Describe the outcome in terms of expected time and resources needed to complete the research and length of time needed for clinical application. (Approximately ½ page)
- (4) **Methods and Research Plan.** Outline the proposed study design and methods. Identify (VA) patient population, sample size, power analysis, and rationale for inclusion or exclusion of population served; (include women and members of diverse ethnic and racial groups). Identify key issues that may have an impact on the success of the proposed project, such as: patient recruitment, participation of specialized personnel, orphan companies, space, and budget. Specify if proposed research will be with animals and, if so, what the time frame is for clinical application. Indicate implications for technology transfer and potential for replication. (Approximately one page)
- (5) **Participants.** Identify PI and Co-PI(s), co-investigators, and collaborators, and state their areas of expertise.
- (6) **Resource and Budget.** Provide estimates of time, up to 3 years of funding (except for pilot projects which are limited to 1 year), full-time equivalent (FTE) staffing, and total cost of the study.
- (7) **Project History.** Indicate whether this study is new, a continuation of an existing project (include years funded), or related to a previously unfunded project. Indicate the Project number, title, and date of the previous related submission.
- (8) **Research Site.** State the name of the facility where the research (patients and laboratory work) will take place (see Item 6 on the LOI cover sheet (VA Form 10-1313-13)).

## 3. SUBMITTING THE LOI

- a. <u>Signatures.</u> The LOI must be signed by the medical center Director and either the ACOS for R&D, R&D Coordinator, or the appropriate designee. LOIs will not be accepted without being processed through the appropriate research office.
- b. <u>Deadlines.</u> The signed, original LOI and six (6) copies must be sent to the following address. With prior approval, e-mail, or facsimile copies will be accepted, but the original must follow.

Merit Review Letter of Intent Coordinator Program Analysis and Review Section (122P) Rehabilitation Research and Development Service Department of Veterans Affairs 810 Vermont Avenue, N.W. Washington, DC 20420

- c. <u>Electronic Submission of LOI.</u> In addition to the requirements for a hard copy submission, an **electronic submission** of the LOI on a disk is required as follows:
- (1) The <u>disk</u> size must be 3 ½ in. The disk format may be high or low density (720K or 1.44 meg.) It must be MS DOS, Windows, Windows 95-98, or NT formatted.
- (2) The <u>disk must be labeled</u> with the date, principal investigator's name, and title of proposed project. The disk must be included with the hard copy LOI submission.

# 4. INQUIRIES AND ADDITIONAL INFORMATION

Inquiries may be directed to RR&D Service, Program Analysis and Review Section (PARS), at 202-254-0255. Please refer also to the RR&D web-site at www.vard.org.

# PREPARING MERIT REVIEW PROPOSALS FOR SUBMISSION TO REHABILITATION RESEARCH AND DEVELOPMENT SERVICE

#### 1. GENERAL

- a. <u>Forms and Instructions.</u> An investigator who plans to submit a pilot study proposal or full research proposal to Rehabilitation Research and Development Service (RR&D) for Merit Review needs to contact the Associate Chief of Staff (ACOS) for Research & Development (R&D) at the local Department of Veterans Affairs (VA) medical facility to obtain information concerning forms and instructions. For pilot study proposals, submit the original and twenty-five copies following the same format used for full research proposals.
- b. <u>Number of Submissions.</u> No proposal should be submitted to more than one VA R&D Service at a time. Principal investigators (PIs) with an ongoing research project or program in any of the VA R&D Services who wish to explore an additional research proposal <u>may submit</u> a proposal to RR&D, subject to Letter of Intent (LOI) approval.
- c. <u>Human Subjects.</u> If the proposed project involves the participation of human subjects, a Report of the Institutional Review Board (IRB) VA Form 10-1223, Report on Subcommittee on Human Studies, is required, as well as VA Form 10-1086, VA Research Consent Form.
- d. <u>Experimental Devices and Investigational Drugs.</u> Clinical studies that include the use of experimental devices or drugs of unproven safety and efficacy are subject to both VA and Food and Drug Administration (FDA) regulations. For clinical investigations involving experimental devices or investigational drugs, an Investigation Exemption application must be submitted to FDA prior to submission of the proposal to RR&D (see VHA Handbook 1200.5).
- e. <u>Withdrawing a Proposal.</u> If an investigator wishes to withdraw a proposal, RR&D must be notified promptly by telephone, followed by a memorandum addressed to the Director, RR&D Service.
- f. <u>Transfers.</u> When a PI with a pending Merit Review proposal transfers to another VA facility, RR&D must be notified in advance of the transfer and must receive the required forms from the new VA facility (including approvals by the facility R&D Committee and appropriate subcommittees). The required forms must be received by RR&D in a timely manner for the proposal to be reviewed.
- g. <u>Routing of Proposals.</u> Each proposal package is routed through the VA medical facility Office of the ACOS for R&D, the R&D Committee, the medical center Director and any other appropriate channels.
  - h. Mailing of Proposals. Proposals are to be sent to:
  - (1) Merit Review Proposal Coordinator Program Analysis and Review Section (122P) Rehabilitation Research and Development Service Department of Veterans Affairs 810 Vermont Avenue, NW Washington, DC 20420

(2) Mailing address for express mail:

Merit Review Proposal Coordinator Program Analysis and Review Section (122P) Rehabilitation Research and Development Service Department of Veterans Affairs 810 Vermont Ave Washington, DC 20420

*NOTE:* The telephone number is 202-254-0255.

- i. <u>Electronic Submission of Proposals.</u> In addition to the requirement for a hard copy, an electronic submission of each LOI is required as follows:
- (1) The <u>disk</u> size must be 3 ½ in. The disk format may be high or low density (720K or 1.44 meg). It must be MS DOS, Windows, Windows 95-98, or NT formatted.
- (2) The <u>Brief Statement of Research Objectives</u> (Abstract) must be file one on the disk. The file format must be plain text or Microsoft Word.
- (3) <u>Graphic</u> pictures, drawings, etc. are not to be submitted electronically. Only the full text (narrative) of the proposal is required, and it must be file two on the disk. The file format must be plain text or Microsoft Word.
- (4) The <u>disk must be labeled</u> with the date, PI's name, project number, and title. The disk must be included with the hard copy proposal submission.

# 2. COMPONENTS OF APPLICATION PACKAGE: Submit the following:

- a. A typed single-spaced <u>original proposal</u>, one side only (unstapled). It will be used as the master file copy. *NOTE: May use black spring clips or rubber bands; do not use silver butterfly clips*. Attach an Optional Form 41, Routing and Transmittal Slip, with the station contact person and phone number.
- b. <u>Ten copies</u> of VA Form 10-1313-1, Merit Review Application, and VA Form 10-1313-2, Summary Description of Program, duplicated back-to-back.
- c. <u>Twenty-five copies</u> of the proposal duplicated back-to-back (stapled). If the proposal is too thick for a staple, then secure with a heavy black clip. Do not use silver butterfly clips. Check for proper page order.
- d. <u>Six copies</u> of up to three selected papers that are representative of the applicant's best work (optional). Publications are <u>not</u> to be placed in an appendix; they need to be enclosed with, not attached to, the proposal.

- e. A <u>memorandum</u> addressed to the Director, RR&D Service (122) with the names of two or more scientists who are qualified to review the proposal will be accepted. Information on reviewers must include their area of expertise and contact information (address, phone numbers, e-mail address, etc.). Include the name of any reviewer who may have a conflict of interest if asked to review your proposal.
- f. If the proposal is a resubmission of a continuation project, a not-funded project, or a deferred project, <u>it is required</u> that six stapled copies of the previously reviewed proposal and six stapled copies of each reviewer's critique be included. Also include fifteen white copies of the Summary Statement from the previously reviewed proposal.
- **3. PAGE FORMAT AND PAGE NUMBERING:** Submit the proposal on 8.5 x 11 inch paper, leaving a 1 inch margin on all sides. Where necessary, use a blank sheet of paper as a continuation sheet for the forms. Type material single-spaced in a type style that prints capital letters one-eighth (1/8) of an inch tall to ensure a clean imprint suitable for reproduction, scanning and readability. Type the PI's name in the lower right portion of each page, and number each page consecutively starting with the face sheet, e.g., Smith-1 to Smith-22. Prepare an index or table of contents and place after VA Form 10-1313-2.
- **4. ORDER OF VA FORMS:** VA Forms 10-1313-1 through 10-1313-8 should be arranged in numerical order.
- **5. VA FORM 10-1313-1, Merit Review Application:** Provide ten copies along with VA Form 10-1313-2.
  - Item 1: Insert Letter of Intent (LOI) number.
  - Item 2: Leave blank.
  - Item 3: Type in **proposal number** assigned by RR&D Service in large numbers.
  - Item 4: Type in **merit review round** (e.g., winter/year or summer/year).
  - Item 5: Complete.
- <u>Item 6:</u> Provide the complete <u>mailing address</u> for the VA medical center or health care facility.
  - Item 7: **Social Security Number.** Complete for PI and Co-PI, if applicable.
  - Item 8: Provide the **date** the PI last submitted a proposal to RR&D for merit review.
- <u>Item 9:</u> The last name of the <u>PI</u> needs to be typed first in capital letters, followed by the first name and initial(s). List telephone number(s) of the PI. The principal investigator needs to be the person responsible for the scientific and technical direction and completion of the work proposed (submission by a single PI is preferred; however, Co-PIs <u>may</u> be identified).

- <u>Item 10:</u> The <u>proposal title</u> is not to exceed 72 typewritten spaces. Be specific and descriptive in the choice of title to assist readers in quickly identifying the overall program objectives. If the proposal title has been changed since a prior submission, or since the LOI was approved, print "NEW TITLE" directly above the typed title.
- <u>Item 11:</u> The <u>amount requested</u> each year is to be the same as the totals listed on other forms within the application. The "total" is total funding requested for all years. Funds may be requested for a period of up to 3 years with a maximum of \$250,000 per year. <u>Proposals may not be submitted for more than 3 years</u>. *NOTE:* Pilot proposals are limited to a maximum of \$50,000 and are funded for 1 year.
- Item 12: VA employment status refers to current or projected salary status of the PI. PIs who have less than a 5/8 part-time appointment must have an eligibility exception in order to submit a proposal. A copy of the 5/8 exception (see App. A, subpar. 2i.) request and the Chief R&D Officer approval memo for each PI and Co-PI must be included with all copies of merit review proposals (including pilots). A current VA paid appointment of at least 5/8 time is required before a research project can be funded (see VHA Handbook 1200.15).
  - Item 13: Mark the appropriate box indicating the PI salary source.
- Item 14: Check appropriate box for <u>NEW or ONGOING</u>. A proposal is considered "new" when it has never been submitted or reviewed by RR&D Service. A proposal is considered "ongoing" when it has been funded for a period of time (1, 2, or 3 years) by RR&D Service. It may also be ongoing (continuation) even though it acquires a new title or there is a major shift in programmatic objectives. In the blank space next to the ONGOING box include entire proposal number and previous review date, (i.e., A2672R; 1/99). If a proposal is a resubmission of an unfunded application, type "Resubmission" in the blank space and list the proposal number and review date. If this application is a pilot, indicate "Pilot" in the blank space at the bottom of item 14. Because each RR&D proposal is considered separately, "No. of Projects in Program" should be one.
- Item 15: Program Code and Cost Center: Insert the three-digit Program Code (822 for RR&D) and the Cost Center number (8122 for RR&D).
- <u>Item 16:</u> Insert the primary research program area and primary specialty area. *NOTE: Primary specialty area is primary board or graduate field of study.* 
  - <u>Items 17 and 18:</u> Complete for each PI and Co-PI.
  - Item 19: Complete and ensure that designated items are included in the proposal.
- <u>Item 20:</u> Beginning with the current year of VA funding, complete and identify the VA Service from which <u>research support</u> is received. Provide the same information for non-VA funding.
- Item 21: Complete for each PI and Co-PI. Insert the <u>date the PI entered on duty</u> at VA, or expected date of entry if appointment is pending. If there has been a break in service, list the

date of most recent appointment. You may indicate prior VA service as parenthetical information.

<u>Signature Blocks:</u> An original <u>signature</u> for the PI(s) and the ACOS for R&D (or designee) is required, with current date. By signing this VA form, the ACOS for R&D certifies that the proposal is complete administratively and all required reviews have been conducted. **Print or type beside or below the signature the name and phone number of a person to contact if administrative issues arise.** 

# 6. VA FORM 10-1313-2, Summary Description of Program

- a. <u>Identifying Information</u>. Check the box marked "project" to indicate that you are describing a project. Provide the identifying information requested: PI name; project title (72 characters or spaces maximum); and key words from the National Library of Medicine permitted Medical Subject Headings (MeSH).
- b. <u>Brief Statement of Research Objectives (Abstract)</u>. The primary purpose of this section is to provide a brief and accurate overview of the proposal. It should include: the research, development, evaluation program objectives (immediate and ultimate), the significance of the research to the VA health care system, and the general research design. A clear, concise description of the proposed study should be provided, however, technical details should not be included. List <u>key words</u> that best describe the scientific disciplines encompassed and the research areas addressed by the research.
- **7. TABLE OF CONTENTS:** List all proposal items and sections, including but not limited to, narrative section; specify page numbers for each major proposal component and element of the proposal (include each part of the Appendix). The Table of Contents is to be inserted immediately after VA Form 10-1313-2.

# 8. VA FORM 10-1313-3, Current Funds and First Year Request

- a. Check the appropriate box to indicate this form applies to a **project** and insert the identifying information (PI(s) name and project title).
- b. List all **personnel** involved in the project, including the PI, under the block titled "PERSONNEL." Provide their names and identify their degree(s).
  - (1) <u>Secretaries</u> are not allowed as study personnel.
- (2) <u>Intergovernmental Personnel Agreements</u> (IPAs) are discouraged. If such arrangements are absolutely necessary for the successful implementation of the project, strong justification with a detailed explanation of estimated costs is required. Identify the name, role in the program and percent of effort under project personnel. Do <u>not</u> include cost. Also identify these IPA personnel under "ALL OTHER EXPENSES" with the title "IPA." The projected cost should be under the section "FIRST YEAR REQUESTED FUNDS."

- c. Under the block titled "<u>ROLE IN PROGRAM</u>" identify for each person their role (i.e., PI, Co-PI, investigator, research technician, programmer analyst) and identify their grade and step.
- d. List the **percent of total professional or technical effort** devoted to the project by all personnel identified.
- (1) List costs for all personnel, which should be proportional to the time devoted to the project. Do not include cost-of-living increases, within grade increases, or anticipated promotions in the personnel category. All personnel projections need to be straight-lined for the duration of the project.
  - (2) List a <u>subtotal for the personnel dollars</u> requested.
- e. The <u>first year request</u> column needs to include all RR&D funds being requested for the projected first 12 months of the project.
- f. The <u>Current Year Funding</u> column needs to include RR&D funds available to the investigator for the 12-month period preceding the first year request if this proposal is an ongoing or continuation project.
- g. If the services of a **consultant** are required, PIs need to consider current applicable VA rules and regulations before developing their budgets. Any consultant paid \$500 or more per consultation, exclusive of expenses, or \$2,500 or more per year must be approved by the Secretary, Department of Veterans Affairs.
- (1) For each consultant listed, <u>provide a justification</u> on VA Form 10-1313-4, Estimated Expenses for Each Year, that indicates the nature of the service to be performed, the fee for each consultation, the amount of travel and per diem, and the number of consultations.
- (2) Expenses related to the consultation, not including payment for services (i.e., <u>travel expenses</u>), should be listed under "ALL OTHER EXPENSES." Travel expenses for non-government personnel should be identified separately from travel for government employees.
- (3) Include <u>with the letters of endorsement</u> at the end of the proposal a letter from each person agreeing to consult and detailing the nature of the consultation. A curriculum vitae for each proposed consultant needs to be included.
- h. List each item of <u>equipment</u> to be purchased and provide justification on VA Form 10-1313-4 for any item for which a need may not be apparent to reviewers or which costs more than \$3,000. For major equipment items, indicate how many similar instruments are located at the facility or in nearby laboratories and/or research areas. Do not submit manufacturer's brochures or photocopies as part of the application. All charges for equipment maintenance must be justified.
  - i. List **supplies** by major types, such as: office supplies, animal supplies, etc.

- j. List <u>all other expenses</u> by major category, including rental and contractual fees.
- (1) <u>IPAs</u> are to be listed here if requested.
- (2) <u>Travel costs</u>, including local travel, are permitted for project staff **if the travel is related directly to the conduct of the research**. List and justify any such travel explicitly on VA Form 10-1313-4. The travel estimate for government employees should be listed separately from any travel needs of non-VA personnel or consultants.
  - (3) <u>Travel costs and registration fees</u> for scientific meetings are **not** to be included (see App. G).
- (4) Expenses for <u>books</u>, <u>journals and professional organization dues</u> are not permitted. Chargeback costs, as well as costs for <u>manuscript preparation</u>, <u>photocopying</u>, <u>printing</u>, <u>publication</u>, and <u>illustrations</u> are not allowed.
- (5) Include the total acquisition charges for <u>animal subjects</u> (type, number, per diem) and total charges for Animal Research Facility maintenance of all animal subjects as itemized on the "ANIMAL COMPONENT OF RESEARCH PROTOCOL" statement.

# 9. VA FORM 10-1313-4, Estimated Expenses for Each Year

- a. Check the appropriate box to indicate this form applies to a **project**.
- b. The total <u>operating expenses</u> for the first year need to be identical to the total indicated on VA Form 10-1313-3, Current Funds and First Year Request, for this project. All differences in the operating expenses between years need to be fully justified in the space provided.
- c. Provide detailed <u>justification</u> for all budget items listed on VA Form 10-1313-3. Use continuation sheets if necessary.
- (1) Detailed descriptions of staff roles are not needed here, but need to be included in the project management plan in the text of the proposal. However, indicate total <u>FTE requested</u> each year. Indicate whether personal service estimates include fringe benefits, etc.
- (2) <u>Travel estimates</u> need to be broken out by year, with a clear distinction between travel to be made by VA and other government employees and travel by non-VA consultants, etc. Government employee travel estimates are to be based on contract airfares and CONUS per diem rates.
  - (3) Where appropriate, provide a breakdown of the project budget by phases and year.
- **10. VA FORM 10-1313-5, Biographic Sketch.** Complete for each investigator and collaborator on the project. Begin with the PI, and any Co-PIs, followed by Co-PIs and other key professional staff (i.e., include all persons who will participate in the design, performance, and professional direction of the proposed research, excluding consultants). Do not include curriculum vitae, either in addition to or in place of VA Form 10-1313-5.

11. VA FORM 10-1313-6, Bibliography. Complete this form for each investigator and collaborator (everyone with a VA Form 10-1313-5). Do not exceed two pages for each investigator and include a chronological list of all the most important and pertinent publications. Abstracts are to be separated from the publications. Do not include publications in preparation or presentations. Use the bibliographic format that has been used for the Research Development Information System (RDIS). Identify those publications that are a result of the most recent period of VA research support, and list them after the collaboration section of the narrative. Literature citations must include the full title of the paper being referenced. If there are no entries on VA Form 10-1313-6, "NONE" should be entered. Do not include curriculum vitae in addition to or in place of VA Forms 10-1313-5 and 10-1313-6.

# 12. VA FORM 10-1313-7, Total VA and Non-VA Research Support, and VA FORM 10-1313-8, Total VA and Non-VA Research/Development

- a. Complete these forms for each investigator and collaborator on the project (each person with a VA Form 10-1313-5 and 10-1313-6 who is listed on VA Form 10-1313-3) with an effort of 10 percent and greater.
- b. Every item listed on VA Form 10-1313-7 must be fully discussed on VA Form 10-1313-8. **Simple statements** such as "there are no budgetary, scientific or administrative overlaps" are not acceptable.
- c. <u>Pending requests</u> must also be included even if there is no current support. Identify the Service and complete RR&D assigned project number, if applicable.
- **13. NON-VA APPLICATIONS:** The abstract of the research plan and budget pages for all funded or pending non-VA applications are to be placed after VA Form 10-1313-8.
- **14. RESUBMISSION:** A resubmitted proposal must include a letter (addressed to the Director, RR&D Service), of not more than three pages, that addresses each concern of the Board Summary Statement. State in detail what changes were made and how it compares to the previous proposal. This letter is to precede the narrative. The new text or changes from the previous proposal are to be reflected in the resubmission in italics. Also include six stapled copies of the latest related reviewed proposal and reviewers' reports (critiques). Include fifteen copies of the Board Summary Statement.
- **15. NARRATIVE DESCRIPTION:** The importance of a well-written, detailed, concise narrative description (not to exceed eighteen pages) cannot be overemphasized. The proposal must be complete for purposes of rigorous peer review without referral to previous proposal submissions, reviews, or extensive appendices, except when such appendices are deemed necessary to present progress of funded research for a continuation proposal.

### a. Rationale and/or Objectives of the Research

(1) **Problem Statement.** Briefly define the problem or recognized need that the proposal is designed to address and include the scope and magnitude of the problem. Explain in the description the rationale for the study and the basis for such determination, with citation of

supportive and appropriate sources. Also cite other efforts undertaken in the respective research area, and why this particular effort is different and needed.

- (2) **Hypotheses or Key Questions.** State the hypothesis or hypotheses to be tested or question(s) to be answered by the project.
- (3) Specific Objectives of the Project with a Projected Timetable. A timetable needs to be provided to indicate expected progress of the study. Be as specific as possible. List the short and long-term objectives of this research. For long-term objectives, identify expected intermediate milestones. Identify an anticipated timetable for achievement of the short-term objectives. This timetable needs to represent a best estimate. It is recognized that early results may lead investigators to alter their specific objectives and timetable. Such alterations may be completely appropriate, but must be formally described and justified in a letter to the appropriate RR&D Program Analyst requesting approval.
- (4) **Current Status.** Describe the current status of work that has been done toward solution of the problem(s) and how this work relates to the hypotheses or questions presented in subparagraph 15a(2) of this Appendix. This description should be sufficiently complete to demonstrate that the principal investigator is aware of all related research. Research supportive of and contrary to the hypotheses should be quoted and discussed. Care needs to be taken to keep this discussion concise and relevant to the problem(s), hypotheses, or questions.
- (5) **Significance of Research.** Explain the potential research significance of the proposed study, both in general and with particular reference to the specific goals and priorities of VA. Identify any unique ideas or potential contributions that may result from this study. State the specific desired outcomes of the proposed study, i.e., how the particular method, concept or device may be transferred to the VA health care delivery system. Identify opportunities that VA may have to improve disabled veterans' quality of life and to contribute to the field of rehabilitation research and development.
- (6) Relevance of the Proposed Work to the VA Patient Care Mission. In a separate paragraph, briefly indicate the relevance of the proposed work to the VA patient care mission and to problems of VA research.

#### b. Background and Work Accomplished

- (1) For <u>completed pilot or continuation projects</u> (give title and entire project number; Box #3 of VA Form 10-1313-1) include a report of the progress made since the study's inception. The report needs to contain detailed information relative to the administrative and scientific completion of the project, whether or not the study met its stated goals, and summarize how funds were appropriately and efficiently used. For continuation projects, state the reasons why additional funds are being requested and provide a projected project completion date.
- (2) Describe <u>accomplishments</u> to date. State the work done that is pertinent to this proposal. Provide reasons why this research is needed. State how it differs from or adds to work previously completed in this field. Charts, graphs, tables, figures, or other material need to be included that succinctly present significant data. These are **not** included in the eighteen-page

count for the narrative, but are not to exceed three pages. References are not to exceed four pages, for a grand total of **no more than twenty-five pages**. List all major publications resulting from work done during the period being reported. Do not include clinical case reports, summaries, or verbatim records of lectures, review articles, or abstracts of papers presented at meetings. Submit six copies of each pertinent paper (no more than three) to support progress (see subpar. 2d).

# c. Work Proposed

- (1) <u>Methodology</u>. Give details of the research plan including descriptive examples of the type of experiments or other work proposed, the major methods to be used, including the specific techniques, e.g., instrumentation, statistical methods to be employed, the kinds of data to be obtained, and the statistical analyses to be used.
- (a) Studies involving human subjects must describe subject selection criteria with details concerning specific inclusion and/or exclusion factors. Informed consent is mandatory. A copy of the proposed informed consent form (ICF) must be included (see VHA Handbook 1200.5 for specific ICF instructions).
- (b) When animals are going to be used in the project, list the number and type, including strains and species. Rationale for choosing the specific species and number must be addressed in the animal component form (ACF), which must be included (see VHA Handbook 1200.07 for specific ACF instructions).
- (2) <u>Resources</u>. Describe the facilities and personnel required for the project. Indicate which are available and which must be obtained, including office and laboratory space, data processing facilities, clinical research wards, access to specific patients, access to VA staff, animal rooms, and major equipment and/or supply items.
- (3) <u>Collaboration</u>. Describe any proposed collaboration with institutions and investigators. Include a description of the role of additional professional persons.
- (4) <u>Literature References.</u> Cite key references and list full title, authors, and dates of publications. Include complete titles of articles as well as books and journals.
- **16. LETTERS OF ENDORSEMENT:** Formal letters from the following must be attached to an RR&D proposal:
- a. The Director of the PI's VA Health Care Facility. The letter must contain statements that:
- (1) The Director understands the potential <u>impact</u> of the proposed research on the facility's organization
  - (2) The Director endorses the proposed project, and

- (3) The <u>space and necessary support</u> of the VA facility will be available if the project is approved for funding by RR&D Service.
- b. The Appropriate Official of any Collaborating Institution. The letter must contain the same information as required in preceding subparagraph 16a(1), subparagraph 16a(2) and, if appropriate, subparagraph 16a(3).
- c. <u>Chairman of the Local VA R&D Committee.</u> A letter indicating the proposal has been reviewed and endorsed by the Chairman of the local VA R&D Committee.
- d. <u>Organizational Elements.</u> An indication of concurrence from each participating or affected organizational element is required.
- e. <u>Consultant(s) or Collaborator(s).</u> The specific role each individual named as a consultant or collaborator has in the project needs to be detailed. A curriculum vitae of each consultant is required.
- **17. INQUIRIES AND ADDITIONAL INFORMATION:** Inquiries may be directed to RR&D Service, Program Analysis and Review Section (PARS), at (202) 254-0255 Refer also to the RR&D website at www.vard.org.

# INSTRUCTIONS FOR SUBMITTING AN APPEAL TO REHABILITATION RESEARCH AND DEVELOPMENT SERVICE REGARDING A DISAPPROVED MERIT REVIEW PROPOSAL

- 1. Rehabilitation Research and Development (RR&D) Service permits submission of a **formal request** to appeal decisions concerning merit reviewed proposals. To be considered, the appeal document must be received by RR&D Service within 4 weeks from the date of the notification letter. Only 'disapproved' proposals may be appealed. Proposals that are not "disapproved," but are assigned priority scores which preclude funding can not be appealed. The appeal process is designed to uncover potential procedural errors, not to resolve differences on scientific points of view between the applicant and the reviewers. The appeal process is not designed to circumvent Merit Review Board recommendations.
- 2. The Merit Review Board **Summary Statement** is the only document acceptable as the basis for an appeal. The individual reviewers' critiques may not be used in the appeal document. As stated in the notification letter, reviewers' critiques are prepared prior to the plenary session, whereas the Summary Statement represents the final recommendations of the Board based on its collective deliberations.
- 3. The appeal document must be limited to <u>five single typewritten pages</u>. It needs to indicate specific points and address possible misinterpretation, misunderstanding or bias by the Board. All information contained in the appeal must have been part of the original proposal. <u>No new information can be introduced in an appeal.</u>
- 4. The appeal must be **reviewed and approved** by the local Research and Development (R&D) Committee, Associate Chief of Staff (ACOS) for R&D, and accompanied by a supporting letter from the Department of Veterans Affairs (VA) facility Director. An original and six copies of the appeal and the supporting documents must be submitted to:

Rehabilitation Research and Development Service Department of Veterans Affairs Program Analysis and Review Section (122P) 810 Vermont Avenue, NW Washington, DC 20420

5. RR&D Service will provide a written determination to the investigator within 60 days after receipt of the formal appeal.

#### PUBLICATION POLICY

- 1. All Department of Veterans Affairs (VA) investigators are required to submit articles emanating from VA Rehabilitation Research and Development (RR&D) funded research to the <u>Journal of Rehabilitation Research and Development (JRRD)</u> for first consideration of publication. Exceptions to this policy will be made at the discretion of the Editor-in-Chief. Support of JRRD is an obligation of every member of the VA RR&D community, and compliance with this policy is a performance measure that will be applied to all funded investigators.
- 2. Articles which are either excepted from this policy, or refused for acceptance by <u>JRRD</u> but accepted by another journal, must list the investigator's VA affiliation and acknowledge VA RR&D as a funding source (primary if that is the case).
- 3. When VA provides half or more of the salary support for the principal investigator, it shall be named first, regardless of whether VA is the primary source of funding or where the funds are administered.
- 4. Reprints of articles appearing in another publication must be sent to RR&D Service: 810 Vermont Avenue, NW (122A); Washington, DC, 20420.
- 5. Advance notice of publication in other sources is required (see VHA Handbook 1200.19).

# GUIDELINES FOR SUBMISSION OF PROGRESS REPORTS AND NARRATIVE SUMMARIES

- **1. REQUIREMENTS:** For all Merit Review research projects: *NOTE:* Continuation of project funding is contingent upon submission of Progress Reports and Narrative Summaries in accordance with these Guidelines.
- a. <u>Progress Reports.</u> Progress Reports must be submitted <u>semiannually</u>, and are due March 15 and September 15. The September Report covers research progress for January 1 through June 30; and the March Report covers research progress for July 1 through December 31.
- b. <u>Narrative Summaries</u>. Narrative Summaries are due <u>March 15 of each year</u>. They summarize research accomplishments for the previous calendar year. *NOTE: Narrative Summaries are published on the RR&D web site at www.vard.org*.
- **2. PROGRESS REPORTS.** Progress reports are due <u>March 15</u> and <u>September 15</u>, and must include the following information:
- a. <u>General Information.</u> Project Number and name(s) of Principal Investigator (PI) and Co-Principal Investigator(s) (Co-PI's). Full names, degrees, and addresses of the PI and Co-PI(s) are to be included, along with updated e-mail addresses, telephone, and fax numbers.
- b. <u>Department of Veterans Affairs (VA) and Non-VA Funding.</u> State whether this research is supported by non-VA, as well as VA, funding (Yes or No). If Yes, provide the full name and address of the non-VA sponsoring organization(s), as well as the amount of funding. Include the sponsor's contact information (e-mail address, telephone, and fax number).

### c. Administrative Progress

- (1) Has the project met its timeline with regard to subject recruitment and/or enrollment data generation and analysis? (Yes or No)
  - (2) Provide a brief summary of project goal attainment versus the proposed timeline.
  - (3) State whether the expenditure of project funds is on schedule. (Yes or No)
- (4) If the project or the expenditure of funds is not on schedule, explain the reasons for the variance, and state what steps have been taken to ensure successful completion of the project within its approved time frame.

### d. Scientific Progress

(1) **Publications.** Provide a complete and accurate list of all publications since the last report, as well as all articles and/or abstracts accepted for publication since the last report. Elements are to be listed in this order: exact title (with only the first letter of the first word

capitalized); author(s) names (last name and initials); publication title; date; volume; issue number; and page numbers.

*Example*: The effectiveness of neurological rehabilitation in multiple sclerosis. Thompson AJ. <u>Journal of Rehabilitation Research and Development.</u> 2000 Jul-Aug; 37(4): 455-61.

- (2) **Submissions for Publication.** List all submissions for publication since last report, using the same format as in preceding subparagraph 2d(1).
- (3) **Media Coverage.** If the project has yielded coverage by the media since the last report, provide details. **NOTE:** PIs are reminded that they are obligated to contact the RR&D Office and the R&D Publications Office promptly to provide timely notification of pending media coverage related to their research.
- (4) <u>Journal of Rehabilitation Research and Development (JRRD)</u>. State planned date to submit next article to <u>JRRD</u> (month and yr.) List topic area and tentative title. *NOTE*: All RR&D funded investigators are expected to submit articles to <u>JRRD</u>. RR&D reserves the right of first refusal for all publications based upon RR&D funded research projects.
- (5) **Implications for Technology Transfer.** Report any information on <u>patents and awards</u> and/or potentially patentable outcomes of the research. Provide a description of the device or technology, and state its novel features and advantages in comparison with the closest known prior state-of-the-art. *NOTE:* Refer to the RR&D web-site for additional information on Technology Transfer reporting requirements for VA investigators: www.vard.org.
- e. <u>Submission of Progress Reports.</u> Progress Reports are to be submitted electronically via email to <u>progress@vard.org</u>. *NOTE:* Visit the web-site, <u>www.vard.org</u>, for additional instructions.
- **3. NARRATIVE SUMMARIES.** Narrative summaries are due <u>March 15</u>, and are to be prepared as documents for publication on the RR&D web-site.
  - a. **Length.** The text of narrative summary must not exceed six hundred words.
  - b. **Organization.** The text needs to contain a:
- (1) Brief summary of the <u>Purpose</u>, <u>Methodology</u>, <u>Progress</u>, <u>Results</u> (<u>Preliminary or Final</u>), since the previous report, and a
  - (2) Brief statement of Implications, Clinical Impact, and Future Plans.
  - (3) Narrative identifying the benefits of this research to veterans.
  - c. **Illustrations.** Do not include figures, tables, or photographs.
- d. <u>Submission of Narrative Summaries.</u> Narrative Summaries must be typed in Microsoft Word and submitted electronically as a Word document, via e-mail, to narsum@vard.org.

**4. INQUIRIES AND ADDITIONAL INFORMATION.** Inquiries may be directed to RR&D Service, Program Analysis and Review Section, at (202) 254-0255. Visit the RR&D web-site, <a href="https://www.vard.org">www.vard.org</a> for additional information and instructions.

#### GUIDELINES FOR SUBMITTING FINAL REPORTS

**1. REQUIREMENTS.** Rehabilitation Research and Development (RR&D) Service requires that Principal Investigators (PI)s provide a comprehensive Final Report, describing in detail the scientific progress of all completed research projects. The report is due no later than 1 month from the completion date of the project, and is to be sent electronically to <u>final@vard.org</u>. **NOTE:** Future consideration of proposals by the investigators is contingent upon the timely submission of a final report as required.

### a. General Information

- (1) This report needs to be of professional quality providing a full description of the study and scientific accomplishments.
  - (2) It needs to include:
- (a) A statement of the problem, background, research methodology, analysis of results, conclusions, and publications.
- (b) Identification of benefits of this research to veterans, implications for technology transfer, and clinical applications.
  - (c) Patents and awards.
- (3) The Associate Chief of Staff (ACOS) for Research and Development (R&D), and the facility Director need to sign the report to indicate local R&D Committee approval.
- b. <u>Publication</u>. The final report will be used for dissemination of information, via the RR&D web-site. Therefore, the report needs to concisely describe the key elements of the study's purpose, design, and results. *NOTE:* Investigators are assured that their research interests will be protected in this publication process.
- **2. FORMAT.** Three hard copies of the report are required, and a plain .TXT file via e-mail. The report is to be printed on pages with at least a 1 inch margin on all sides, and in a standard typeface such as 12 point courier font, using word processing or desktop publishing software. Use a laser or letter quality line printer. The plain .TXT file is to be sent by e-mail to <a href="mail@vard.org">final@vard.org</a>.

### a. Outline of Report

- (1) Title Page.
- (2) **Table of Contents.** This needs to be fairly detailed. List major headings and subheadings and their initial page number.
  - (3) Key words.

(4) <b>Introduction.</b> <i>NOTE:</i> Include research objectives, background (two to three paragraphs), and literature review.
(5) Methods.
(6) Results (in detail).
(7) Discussion and implications (in detail).
(8) Clinical significance of the research.
(9) Potential for technology transfer.
(10) Publications.
(11) References.
(12) <b>Index.</b>
(13) Appendices.
b. Content of Report
(1) Title Page. Include the:
(a) Title of project;
(b) Full names;
(c) Degrees;
(d) Addresses, telephone and fax numbers, and e-mail addresses of the PI and Co-PI(s); and
(e) The principal research site.
(2) <b>Key Words.</b> Three to ten key words, preferably terms from the Medical Subject Headings (MeSH) from <u>Index Medicus</u> need to be provided.
(3) <b>Introduction.</b> Encompass the project's purposes and context. Why was this project started? What did it set out to accomplish and why? What was the purpose of the study?
(4) <b>Background and Literature Review.</b> This should be a logical extension of the introductory remarks. Referring to appropriate literature and other information sources, lay the foundation for the research project and the approach taken. Describe the conceptual framework for the study. What does the current project contribute to scientific knowledge in general or the VA health care system in particular?

- (5) **Methods.** What was done? How was it done? Where and when was it done? Who did it? Were any design changes required after the initial conceptualization of the study? Who were the subjects and how were they selected? Details need to be sufficient to permit another competent investigator to replicate your research.
- (6) **Results.** What was found? Several subsections may be needed to explicate findings in detail. If complex analytic methods were used to derive results, their essence needs to be described in an introductory section, as should sources of data, if the reader needs this information to understand the results.
- (7) **Discussion and Implications.** What is the meaning of what was found? What is the potential impact on health care? Who is most likely to benefit from the results of this research?
- (8) **Publications.** Complete and accurate list of recent publications for the past 2 years including publication title, date, volume, issue number, and page numbers.
- (9) **References.** References are to be placed at the end of the report. **NOTE:** If the report is set up in chapters, references may be placed at the end of each chapter. In any case, use a consistent and widely accepted format, such as that recommended in the <u>American Medical Association Manual of Style</u> of the National Library of Medicine Recommended Formats for Bibliographic Citation. **NOTE:** Authors are responsible for the accuracy of their references.
- (a) References are to be typed separately, double-spaced, and numbered consecutively in the order in which they are first mentioned in the text.
- (b) References first cited in tables or figure legends are to be numbered so that they will be in proper sequence with references cited in the text.
- (c) "Unpublished observations" or "personal communications," for which the author has secured permission of the person cited, need to be treated as footnotes and not be included in the numbering of the references.
- (10) **Index.** An index listing key words and phrases (preferably using MeSH terms) with page citations can be very helpful to readers interested in specific topics covered in the report. Most word processing software programs include the means to automatically create an index as the report is generated.
  - (11) **Illustrations.** Include figures, tables, or photographs.
- (a) <u>Figures, Graphics and Photos.</u> Figures, graphics and photos may be used for clarifying the text.
  - (b) Tables. Tables are not to duplicate material in text or illustrations.
- (c) <u>Mathematical Formulae</u>. Narrative notes of explanation and definitions of terms needs to accompany mathematical treatments.

- (d) <u>Metric System.</u> The Metric System is requested for use in all quantities in text, tables, and figures.
- **3. CORRESPONDENCE.** The final report must be approved by the facility R&D Committee, and transmitted, through the ACOS or Coordinator of R&D, to RR&D Service.
  - a. The final report is to be mailed to:

Merit Review Final Report Coordinator Program Analysis and Review Section (122P) Rehabilitation Research and Development Service Department of Veterans Affairs 810 Vermont Avenue, NW Washington, DC 20420

b. If sent via Federal Express, Express Mail, or other carrier that hand delivers, the following address is to be used:

Merit Review Final Report Coordinator Program Analysis and Review Section (122P) Rehabilitation Research and Development Service Department of Veterans Affairs 810 Vermont Avenue, NW Washington, DC 20420

NOTE: Phone: (202) 254-0255.

**4. INQUIRIES AND ADDITIONAL INFORMATION.** Inquiries may be directed to RR&D Service, Program Analysis and Review Section (PARS), at (202) 254-0255. For additional information, visit the RR&D web-site: www.vard.org.

#### **MERIT REVIEW TRAVEL**

- **1.** <u>Purpose.</u> This Appendix outlines the steps required to obtain Rehabilitation Research and Development (RR&D) travel funding for Principal Investigators (PIs) of approved Merit Review awards.
- **2.** <u>Policy.</u> The Director, RR&D, has established a limit of up to \$1,000 for PI travel for one trip per funded Merit Review project. This policy was adopted to meet RR&D's commitment to provide support for investigators to present their research findings, while maximizing available dollars to support Merit Review research. For RR&D funding of investigator travel, the PI must present data analysis results from the PI's currently funded Merit Review project. The PI must have a minimum of 6 months of research findings on this specific project before travel funds may be requested.
- **3.** <u>Procedure.</u> The Department of Veterans Affairs (VA) medical center Administrative Officer (AO) for R&D must forward a written request via email or fax to the RR&D Budget Office. The request must include the following information:
  - a. PI's name.
  - b. Project identification number.
  - c. Project start and end dates.
  - d. Amount of travel funds requested.
  - e. Location of trip.
- f. Purpose of trip, and <u>justification of request</u>, including a <u>statement of the research results</u> to be presented from current Merit Review project.

**NOTE:** Only one trip may be requested per Merit Review award.